

75. (New) A surgical fastener as recited in claim 74 wherein a retaining member having a portion passing through the pierced tissue or tissues and graft is bent to substantially align with said second section.

76. (New) A surgical fastener as recited in claim 74 wherein at least a portion of said piercing element is passed through a hole defined by said second section.

REMARKS

Claims 1-16, 18, 19, 21-23, 26-31, 36-55, and 67-76 are currently pending. All but claims 67-76 have been rejected. New Claims 68, 70-73 and 76 are drawn to Species 2; new claims 69 and 75 are drawn to Species 1; new claims 67 and 74 are generic to both. Applicants realize that the claims drawn to Species 2 read on a non-elected species but assert that they depend from generic claims. They are presented for purposes of reinstatement upon allowance of the generic claims. Claims 26, 27, 28, 31 and 36 are amended as set forth above. The new claims and claim amendments are believed to be supported by the Specification as filed.

Election/Restriction

Applicants note that the Examiner does not appear to have commented on Applicants' previous assertion that certain claims pending in the application are generic, reading on both Species 1 and 2. To aid the Examiner's consideration of this point, Applicants note the manner in which these species read on various claims as they presently stand. For Species 1 as described by claim 26, element 3 and/or 4 is the "first member," element 2 is the "second member" and element 1 is the "third member." For Species 1 as described by claims 31, 36, 43-47, and 74 element 2 is the "first section" and element 1 is the "second section." In other claims, element 1 is the flange, element 2 is the base, element 3 is the pin and element 4 is the needle or piercing element. For Species 2 as described by claim 26, element 404 is the "first member," element 405 is the "second member" and element 407 is the "third member." For Species 2 as described by claims 31, 36, 43-47, and 74 element 405 is the "first section" and element 407 is the "second section." This pattern of correspondence for each species carries through the new claims as well.

In view of this understanding of the invention, both Species 1 and 2 read on at least claims 26, 31, 36, 67 and 74 describing the generic staple in isolation and claims 43-47 employing the generic staple in a system. Applicants request acknowledgement of the generic nature of these claims, since upon allowance of the same, any of the new claims added to the application withdrawn by the Examiner which only describe Species 2 are intended to be rejoined.

Drawings

Regarding the Drawings, Applicants shall comply with the Examiner's request and submit formal drawings when the application is allowed.

Claim Rejections - 35 U.S.C. § 102

Rejection of claim 1-4 and 26-31 under 35 U.S.C. 102(b) over Barrows et al. ('917)

Regarding the rejection of claims 1-4, Applicants note that the Barrows in no way discloses a fastener comprising a base having a substantially planar surface as required by each of the rejected claims. In fact, in the Summary of the Invention at column 2, lines 24-27, the portion of the Barrows staple the Examiner asserted as corresponding to the "base" in Applicants' invention is disclosed as having a wire-like (potentially hollow) construction. This is not "substantially planar" as required by claim 1. This distinction is further clarified by the figures of the reference which depict shading of the staple wire which indicates structure having a rounded shape. Therefore, the rejections should be withdrawn.

With respect to claims 26-28, the Barrows device does not have a first member "with at least a portion adapted to pass through tissues, or tissue and graft" as required by claim 26. Applicants note that it is well-settled that "adaptation" claim language provides structural limitations to a claim. Clearly, such structural limitations may serve to distinguish over a reference. See *e.g. In re Venezia*, 189 U.S.P.Q. 149, 151-52 (C.C.P.A. 1976), (The claim language "'a pair of sleeves ... each sleeve of said pair adapted to be fitted over the insulating

jacket of one of said cables' ... imparts a structural limitation to the sleeve.") As such, considering the fact that no portion of the ends (8) of the Barrows staple are disclosed as passing through tissues or tissue and graft or are capable of doing so while still maintaining any utility for the device as a fastener, the rejection to these claims requiring such adaptation should be withdrawn.

Regarding claims 31 and 36, the claims have been amended to include only a single needle. According to the Examiner's interpretation of Barrows, the reference must be read to disclose two. Therefore, withdrawal of the rejection as to these claims is requested.

Rejection of claims 5-8, 10, 12-15, 19, 21-23, 43-45, 47-49 under 35 U.S.C. 102(b) over McGarry et al. ('479)

As with the claims above, the "adapted for" language in claim 5 distinguishes it from the reference. The language of claim 5 requiring the staple holder described to be "adapted to engage a staple and a needle" and the staple forming member to be "adapted to bend the pin over a substantial portion of the base ..." does not merely recite functional language drawn to intended use. These clauses each denote structure the reference does not have. The reference device is not constructed in a way so it is capable of performing as the structure is adapted to do in claim 5. Therefore, the structure is different and withdrawal of the rejection to claim 5 and claims 6-8 and 10 which depend from it is requested.

Regarding claim 12, Applicants note another established legal principle that requires withdrawal of the rejection of claim 12 and also claims 13-15 which depend from it. Namely, when "means plus function" language falling under 35 U.S.C. §112, ¶6 is employed in a claim, it must be interpreted in view of the corresponding structure in the Specification. Once the Examiner takes this into account, it will be appreciated how the staple forming means and staple holder means set forth in claim 12 are not anticipated or made obvious by McGarry which discloses a much different structure than Applicants.

Regarding claim 19 and claims 21-23 which depend from it, McGarry does not disclose every limitation of the method described by claim 19. Claim 19 describes:

“actuating the staple forming member to bend the pin over a substantial portion of the base and to bend the flange over a substantial portion of the pin, so that the staple is substantially closed”

The claimed action (particularly the italicized text) clearly is not disclosed in McGarry.

Therefore, the rejections should be withdrawn.

With regard to claim 43, §112, ¶6 should be applied to the claimed “means for” performing the various functions disclosed. Without question, the structure in Applicants’ Specification that corresponds to the claimed means is novel and non-obvious in view the reference. Therefore, withdrawal of the rejection of claim 43 and claims 45 and 47-49 which depend from it is requested.

Rejection of claim 5, 9, 12, 16, and 43-46 under 35 U.S.C. 102(b) over European Patent (‘441)

Here, Applicants note that the characterization of the reference asserted to anticipate the rejected claims is improper. The instrument in the ‘441 application does not disclose an elongated shaft with various staple holder and forming apparatus at its end as required by rejected claims 5, 9, 12, 16, and 43-46. Element 106 is no more a shaft than element 110 is a handle as described by Applicants’ claims. What is disclosed in the ‘441 reference is a pliers-like apparatus. The two distinct elements 106 and 102 of the stapler are independent pieces that are only associated with each other when the apparatus is in a closed position and not properly called a “shaft” as asserted by the Examiner. Figure 13 of the reference clearly demonstrates why the two pieces are not properly characterized as such. In this figure, the components are shown splayed apart indicating that they are indeed discrete or distinct pieces which do not form a shaft at all. Therefore, the rejection of the claims should be withdrawn since the reference does not meet the claims’ limitations.

Furthermore, especially with regard to the rejection of claim 5, the arguments made above noting the significance of the “adaptation” language are applicable here with respect to the ‘441 reference. As such, Applicants respectfully request that the Examiner reconsider the import

of the claim language and recognize that it properly serves to distinguish over the reference. Also, as similarly noted with respect to claims 12 and 43 above, Applicants request that the Examiner reconsider the claims in view of §112, ¶6 as applicable.

Claim Rejections - 35 U.S.C. § 103

Rejection of claims 11 and 18 under 35 U.S.C. 103(a) over McGarry et al. ('479)

Applicants note that the rejected claims depend from claims believed to be allowable and should therefore be found allowable as well. Further, the reference cited neither discloses nor suggests the features of the claims rejected for obviousness or those discussed above from which these claims depend.

Contrary to what the Examiner has asserted, it would not have been a mere matter of design choice to size the device to have the claimed dimensions. No modification of size to reach Applicants' claimed invention is suggested in the reference since such a modification would serve no apparent purpose since elements 102 and 106 are splayed apart during operation to far exceed whatever size the supposed "shaft" the Examiner asserted the reference disclosed displays. In contrast, the sizing Applicants' invention as described in claims 11 and 18 has special functional significance since it facilitates endoscopic surgery. Therefore, the rejection should be withdrawn.

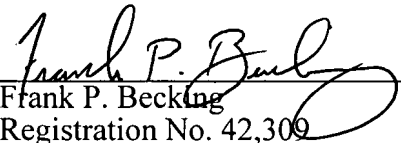
CONCLUSION

No new matter is believed to have been added by the amendments or new claims. Further, Applicants believe that each matter of substance raised by the Examiner has been addressed. Also, in the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 388402000900.

However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: May 12, 1999

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